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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,301	04/19/2006	Toshikazu Nakamura	2006_0047A	7075

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EXAMINER	
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ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,301	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-34* is/are pending in the application.

4a) Of the above claim(s) *1-11,19 and 23-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16-18,20-22 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 18 July 2008, in which claims 12-14, 16-18, 20-22 and 34 are amended to change the scope and breadth of the claim, and claim 15 is canceled.

This application is the national stage entry of PCT/JP05/05741, filed 28 Mar 2005; and claims benefit of foreign priority document JAPAN 2004-097047, filed 29 Mar 2004; currently an English language translation of this foreign priority document has not been filed.

Claims 1-14 and 16-34 are pending in the current application. Claims 1-11 and 23-33, drawn to non-elected inventions, are withdrawn. Claim 19, drawn to non-elected species, is withdrawn. Claims 12-14, 16-18, 20-22 and 34 are examined on the merits herein.

Objections Withdrawn

Applicant's Amendment, filed 18 July 2008, with respect to objections to claim 13 has been fully considered and is persuasive, as amended claim 13 now further limitsthe subject matter of a previous claim.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 18 July 2008, with respect to claim 34 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claim 34 finds sufficient written description to support the claimed invention.

This rejection has been **withdrawn**.

The following modified grounds of rejections are necessitated by Applicant's Amendment, filed 18 July 2008, in which claims 12-18, 20-22 and 34 are amended to change the scope and breadth of the claim.

Claim Rejections - 35 USC § 102

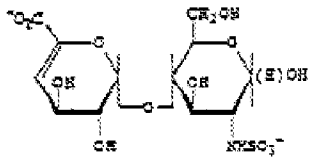
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended Claims 12-14, 16-18, 20-22 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalon et al. (US Patent Application Publication 2003/0130230, published 10 Jul 2003, of record) with evidence provided by Seidel et al. (British Journal of Haematology, 1999, 105, p641-647, of record) and Rabenstein (Nat. Prod. Rep. 2002, 19, p312-331, cited in PTO-892).

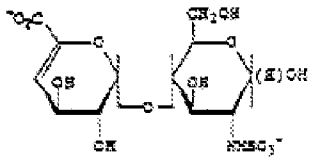
Cahalon et al. discloses a method for treating symptoms associated with the development and metastasis of malignancies comprising administering a heparin-derived saccharide compound (page 7, paragraphs 58, 59 and 52). Cahalon et al.

discloses the administration of the compound to a mammal, a mouse (page 11, paragraph 77). Cahalon et al. discloses the use of compound DS 1145



(page 16, table entry DS 1145), the elected specie of compound, meeting the limitations of instant claims 12-15, 18, 20, 21 and 34. Cahalon et al. discloses the compound isolated from low molecular weight heparin or produced by the action of heparinase on natural sources of heparin, or high molecular weight heparin (page 3, paragraph 24), meeting the limitation of instant claim 16. Cahalon et al. envisions compounds having antimetastatic and anti-inflammatory activity having negligible anticoagulant activity (page 2, paragraph 16), meeting the limitation of instant claim 22. Cahalon et al. discloses the heparin-derived saccharide compound exhibits a regulator effect that includes both up regulation and down regulation of cytokine activity and may elicit the secretion of active cytokine (page 6, paragraphs 31 and 32).

As evidenced by Seidel et al., it is known that soluble heparin molecules induce an increase in the cytokine hepatocyte growth factor (HGF), which is involved in the process of cancer growth and metastasis (page 641, left column, paragraph 1 and right column, paragraph 2). Seidel et al. discloses heparin induces and immediate rise of serum HGF (page 642, left column, paragraph 3). Therefore, it is apparent from what is disclosed that one practicing the method disclosed by Cahalon et al. would inherently be practicing the instantly claimed method of promoting HGF production.

Cahalon et al. is silent to suppressing anti-blood coagulation activity and LPL releasing activity of the heparin fragment. However, Rabenstein provides evidence showing these properties are inherent to the compound  . Rabenstein discloses a unique pentasaccharide sequence is required for the anticoagulation activity of heparin (page 327, left column, paragraph 3). Rabenstein discloses the smallest heparin sequence that bound to LPL was a decasaccharide (page 327, right column, paragraph 3). As the compound disclosed by Cahalon et al. is a disaccharide, it does not meet the requirements of a pentasaccharide or decasaccharide necessary to exhibit anti-blood coagulation activity or LPL releasing activity.

Note that "promoting HGF production" and "suppressing anti-blood coagulation activity and LPL releasing activity of the heparin fragment" is merely considered to be new function or the mechanism of action of a treatment, administration of said compound to a mammal in need thereof. It has been settled that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not make the claim patentable as set forth in the 102(b) rejection above.

Moreover, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps, i.e., administering the **same compound** in the effective amount to the same or similar patient population, are already known even though Applicant has proposed or claimed the mechanism (e.g.,

promoting HGF production and suppressing anti-blood coagulation activity and LPL releasing activity of the heparin fragment). Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or substantially identical method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

That applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. Thus, the method steps in Cahalon et al. are the same as the method claimed herein. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Claim 17 recites a method of using a product drawn to a product-by-process. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re

Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). See MPEP 2113.

Response to Applicant's Remarks:

Applicant's Remarks, filed 18 July 2008, have been fully considered and found not to be persuasive.

Applicant remarks that the instantly claimed compound is produced by a different method. However, the chemical structure of the product produced by the method disclosed in Cahalon et al. is the same as the chemical structure of the instantly claimed product. Where the claimed and prior art products are identical or substantially identical in structure, a *prima facie* case of anticipation has been established. Products of identical chemical composition can not have mutually exclusive properties. See MPEP 2112.01 I and II.

With regard to the instantly claimed mechanism of action of a treatment, the mechanism of action of a treatment does not have a bearing on the patentability of the invention if the method steps are already known. Further, as evidenced by Seidel et al. and Rabenstein, there is reason to believe the method of treatment disclosed by

Cahalon et al. inherently includes functions that are newly cited. It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Evidence of secondary considerations, such as unexpected results, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. See MPEP 2131.04.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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